TriClip™ G4

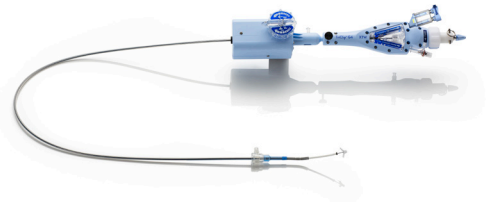
Transcatheter Tricuspid Valve Repair

TRICLIP™ G4 SYSTEM SPECIFICATIONS

TRICLIP™ G4 SYSTEM

PRODUCT CODE	DESCRIPTION	PIECE COUNT
TCB0302-NT	**TriClip™ G4 NT bundle** [Contents: one (1) TCDS0302-NT, one (1) TSGC0202]	2
TCB0302-NTW	**TriClip™ G4 NTW bundle** [Contents: one (1) TCDS0302-NTW, one (1) TSGC0202]	2
TCB0302-XT	**TriClip™ G4 XT bundle** [Contents: one (1) TCDS0302-XT, one (1) TSGC0202]	2
TCB0302-XTW	**TriClip™ G4 XTW bundle** [Contents: one (1) TCDS0302-XTW, one (1) TSGC0202]	2
TCDS0302-NT	**TriClip™ G4 NT Clip Delivery System**	1
TCDS0302-NTW	**TriClip™ G4 NTW Clip Delivery System**	1
TCDS0302-XT	**TriClip™ G4 XT Clip Delivery System**	1
TCDS0302-XTW	**TriClip™ G4 XTW Clip Delivery System**	1
TSGC0202	**TriClip™ Steerable Guide Catheter**	1

TCDS0302



TSGC0202

TRICLIP™ G4 SYSTEM DIMENSIONS

COMPONENT	DIMENSION			
DELIVERY CATHETER				
Extended Length (from Sleeve curved at 90 degrees)	> 5.6cm			
STEERABLE SLEEVE				
Working Length	109.5 cm			
Catheter Distal Shaft Outer Diameter	5.3 mm (16 Fr)			
TRICLIP™ G4 IMPLANT	**G4 NT**	**G4 NTW**	**G4 XT**	**G4 XTW**
Grasping Width at 120 degrees (Figure 1A, Figure 2A)	17 mm	17 mm	22 mm	22 mm
Clip Width at 180 degrees (Figure 1B and 2B)"	20 mm	20 mm	25mm	25mm
Arm Length (Coaptation Length) (Figure 1C, Figure 2C)"	9 mm maximum	9 mm maximum	12 mm maximum	12 mm maximum
Arm Width (Figures 1D and 2D, Figures 1E and 2E)	4 mm maximum	6 mm maximum	4 mm maximum	6 mm maximum
STEERABLE GUIDE CATHETER				
Working Length	80.0 cm			
Catheter Shaft Inner Diameter	5.5 mm (16 Fr)			
Catheter Shaft Outer Diameter	8.4 mm (25 Fr)			
Catheter Distal Tip Diameter	7.7 mm (23 Fr)			
DILATOR				
Working Length	122.0 cm			
Shaft Inner Diameter	1.0 mm (3 Fr)			
Shaft Outer Diameter	5.4 mm (16 Fr)			
Distal Tip Outer Diameter	1.5 mm (4 Fr)			

TRICLIP™ G4 NT IMPLANT DIMENSIONS:

FIGURE 1A
Grasping Width at 120 degrees

FIGURE 1B
Clip Width at 180 degrees

FIGURE 1C
Arm Length

FIGURE 1D
NT Arm Width

FIGURE 1E
NTW Arm Width

TRICLIP™ G4 XT IMPLANT DIMENSIONS:

FIGURE 2A
Grasping Width at 120 degrees

FIGURE 2B
Clip Width at 180 degrees

FIGURE 2C
Arm Length

FIGURE 2D
XT Arm Width

FIGURE 2E
XTW Arm Width

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
Always check the regulatory status of the device in your region.

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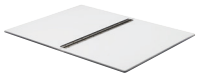
REQUIRED ACCESSORIES

PRODUCT CODE	DESCRIPTION	PIECE COUNT
SZR01ST	Stabilizer	1
LFT01ST	Lift	1
PLT01ST	Support Plate	1


SZR01ST


LFT01ST


PLT01ST

One (1) Silicone Pad, three (3) Fasteners (All are included sterile with the Steerable Guide Catheter)

ADDITIONAL REQUIRED EQUIPMENT NOT INCLUDED

- Step-up dilators
- 260 cm of 0.9 mm (0.035") super stiff exchange length guidewire
- High pressure three way stopcocks (5)
- Arterial high pressure extension tubing (3)
- 50-60 cc syringes with luer fitting (2)
- 1000 ml pressure bags (2)
- Sterile IV tubing with thumbwheel occluders (2)
- Heparinized sterile saline solution (2) 1 liter bags
- Rolling IV Pole
- Sterile Basin

HOW SUPPLIED

Contents:

TriClip™ G4 Delivery System contents:

- One (1) TriClip™ G4 Delivery System with the TriClip™ G4 Implant, one (1) TriClip™ G4 Implant Card
- Steerable Guide Catheter contents:
- One (1) Steerable Guide Catheter, one (1) Dilator, one (1) Silicone Pad, three (3) Fasteners

Sterile:

The TriClip™ G4 Delivery System and TriClip™ Steerable Guide Catheter are sterilized with ethylene oxide gas and provided in a thermoformed tray with lid, in a sealed pouch. Parts of the devices that are in either direct or indirect contact with circulating blood are non-pyrogenic. Note the product "Use By" date specified on the package. DO NOT use if the "Use by" date has passed. These devices are intended for single-use only. Do not reuse. Do not resterilize.

This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and / or chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to contamination due to narrow gaps and / or spaces and diminished safety and / or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user. Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged. Do not reinsert the TCDS or TriClip™ Implant after single use in patient.

The white Guide tip shape retainer and transparent protective tubing are provided sterile and preinstalled on the distal tip of the Steerable Guide Catheter. The Fasteners and the Silicone Pad used with the Stabilizer are provided sterile with the Steerable Guide Catheter. The Dilator, Fasteners and the Silicone Pad are intended for single use only. Do not reuse. Do not resterilize, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Non-sterile:

CAUTION: The Stabilizer, Support Plate and Lift are provided non-sterile. Follow the cleaning and sterilization instructions provided with the Stabilizer, Support Plate and Lift.

Storage:

Handle with care. Store in original packaging. Keep dry. Keep away from sunlight.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the TriClip™ G4 Implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)
- Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, TriClip™ G4 Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a pair of TriClip™ G4 Implants extends approximately 40 mm beyond the TriClip™ G4 Implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.** Always check the regulatory status of the device in your region.
Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott 3200 Lakeside Dr., Santa Clara, CA. 95054 USA

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